

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

F B Rice & Co
605 Darling Street
BALMAIN NSW 2041

R E C E I V E

29 MAR 2004

F. B. RICE & C

PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing
(day/month/year)

26 MAR 2004

REPLY DUE

within **TWO MONTHS**
from the above date of mailing

Applicant's or agent's file reference
116833

International Application No.
PCT/AU2003/001687

International Filing Date (day/month/year)
18 December 2003

Priority Date (day/month/year)
19 December 2002

International Patent Classification (IPC) or both national classification and IPC

Int. Cl. ⁷ A61F 11/04, A61N 1/05

Applicant

COCHLEAR LIMITED et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:.

- I Basis of the opinion
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

3. The **FINAL DATE** by which the international preliminary examination report must be established according to Rule 69.2 is:
19 April 2005

4. The applicant is hereby invited to reply to this opinion.

When? See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established.

If no response is filed by 1 month before the **Final Date**, the international preliminary examination report will be established on the basis of this opinion.

Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least 3 months before the **Final Date** by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

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WRITTEN OPINION

International application No.

PCT/AU2003/001687

I. Basis of the opinion

1. With regard to the elements of the international application:*

- the international application as originally filed.
- the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- the claims, pages , as originally filed,
 pages , as amended under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- contained in the international application in printed form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages
- the claims, Nos.
- the drawings, sheets/fig.

5. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"

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IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- restricted the claims.
- paid additional fees.
- paid additional fees under protest.
- neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

The International Preliminary Report on Patentability (Chapter II) has been drawn up in respect of the entire international application but the International Preliminary Examining Authority is of the opinion that the application does not appear to comply with the requirements of unity of invention as set forth in the PCT regulations (Article 34(3), Rule 68(1) PCT).

The separate groups of invention are:

1. Claims 1-7, 11. It is considered that a seal that is pierceable by a stiffening element but which at least substantially seals the lumen following removal of the stiffening element therefrom comprises a first "special technical feature".

NOTE : Claims 8-10. These claims define a plug member (that is positionable within an orifice of a lumen). No special technical features are defined that could be considered to characterise the plug member. In fact an example of such a plug is clearly disclosed in WO 2002/028473.

2. Claims 12-19. It is considered that a sealing member mountable to the stiffening member, wherein the stiffening member is movable relative to the orifice of the lumen between a first position in which the sealing member mountable thereon does not seal the lumen and a second position in which the sealing member at least substantially seals the lumen comprises a second "special technical feature".
3. Claims 20-24. It is considered that a compression member adjustable between a first configuration in which the compression member does not compress a portion of the lumen and a second configuration in which the compression member does compress the lumen comprises a third "special technical feature".
4. Claims 25-29. It is considered that the lumen having at least one first portion of a first diameter and at least one second portion having a diameter less than that of said at least one first portion comprises a fourth "special technical feature".

Continued on supplemental sheet

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- all parts.
- the parts relating to claims Nos.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-7, 11-33	YES
	Claims 8-10	NO
Inventive step (IS)	Claims 1-7, 11-33	YES
	Claims 8-10	NO
Industrial applicability (IA)	Claims 1-33	YES
	Claims	NO

2. Citations and explanations**NOVELTY (N) AND INVENTIVE STEP (IS)**Claims 8-10**WO 2002/028473 A1 (COCHLEAR LIMITED) 11 April 2002**

This document clearly discloses a plug member that is positionable within an orifice of a lumen of an elongate member of an implantable tissue-stimulating device. Refer to the plug 19 shown in figure 1.

Claims 1-7, 11-33

These claims are novel and inventive as no prior art document discloses a lumen being able to receive a stiffening element through the orifice, and a seal that is pierceable by the stiffening element but which at least substantially seals the lumen following removal of the stiffening element therefrom.

INDUSTRIAL APPLICABILITY (IA)

The subject matter of the claims finds application in the medical/human necessities industry.

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PCT/AU2003/001687**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 9 does not define any features that characterise the plug member. It merely defines a plug member "that is positionable" within an orifice and therefore relies on the result to be achieved to define its features.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of IV

5. Claim 30. It is considered that at least a portion of the lumen coated with a layer of material that swells following exposure to bodily fluids comprises a fifth "special technical feature".
6. Claims 31-33. It is considered that the lumen in the region adjacent the orifice decreases in diameter away from the orifice into the elongate member for a length comprises a sixth "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

Since all the inventions were searched, the international preliminary examination is based on all claims (without additional effort) without extra charge.